CLAIMS

WHAT WE CLAIM IS:

1. A hybridization assay probe for use in determining the presence of HPV Type 16 nucleic acid in a sample, said probe comprising an oligonucleotide up to 100 bases in length and having a base region that is at least 70% complementary to an at least 10 contiguous base region present in a nucleic acid target region selected from the group consisting of SEQ ID NO:5, SEQ ID NO:6, SEQ ID NO:7, SEQ ID NO:8, SEQ ID NO:9, SEQ ID NO:10, SEQ ID NO:11, SEQ ID NO:12, SEQ ID NO:17, SEQ ID NO:18, SEQ ID NO:19, SEQ ID NO:20, SEQ ID NO:25, SEQ ID NO:26, SEQ ID NO:27, SEQ ID NO:28, SEQ ID NO:29, SEQ ID NO:30, SEQ ID NO:31, SEQ ID NO:32, SEQ ID NO:33, SEQ ID NO:34, SEQ ID NO:35 and SEQ ID NO:36, wherein said probe forms a detectable probe:target duplex with said target region under selective stringency hybridization conditions, and wherein said probe does not form a detectable probe:non-target duplex with nucleic acid from HPV Type 6, 11, 31, 33, 35, 39, 45, 51, 52 and/or 58 under said conditions.

2. A nucleic acid hybrid formed between said probe and said target region of claim 1.

3. A kit comprising:

said probe of claim 1; and

an amplification oligonucleotide for use in amplifying HPV Type 16 nucleic acid in a sample, said amplification oligonucleotide being up to 100 bases in length and having a base region that is at least 70% complementary to an at least 10 contiguous base region present in a nucleic acid target region selected from the group consisting of SEQ ID NO:1, SEQ ID NO:2, SEQ ID NO:3, SEQ ID NO:4, SEQ ID NO:13, SEQ ID NO:14, SEQ ID NO:15, SEQ ID NO:16, SEQ ID NO:21, SEQ ID NO:22, SEQ ID NO:23, SEQ ID NO:24, SEQ ID NO:37, SEQ ID NO:38, SEQ ID NO:39, SEQ ID NO:40, SEQ ID NO:85, SEQ ID NO:86, SEQ ID NO:87, SEQ ID NO:88, SEQ ID NO:89, SEQ ID NO:90, SEQ ID NO:91, SEQ ID NO:92, SEQ ID NO:93, SEQ ID NO:94, SEQ ID NO:95 and SEQ ID NO:96, wherein said amplification oligonucleotide optionally includes a base sequence that is recognized by an RNA polymerase.

4. A kit comprising:

said probe of claim 1; and

a set of amplification oligonucleotides for use in amplifying HPV Type 16 nucleic acid in a sample, said set including first and second amplification oligonucleotides, wherein each of said first and second amplification oligonucleotides is up to 100 bases in length and has a base region that is at least 70% complementary to an at least 10 contiguous base region present in a nucleic acid target region selected from the group consisting of SEQ ID NO:1, SEQ ID NO:2, SEQ ID NO:3, SEQ ID NO:4, SEQ ID NO:13, SEQ ID NO:14, SEQ ID NO:15, SEQ ID NO:16, SEQ ID NO:21, SEQ ID NO:22, SEQ ID NO:23, SEQ ID NO:24, SEQ ID NO:37, SEQ ID NO:38, SEQ ID NO:39, SEQ ID NO:40, SEQ ID NO:85, SEQ ID NO:86, SEQ ID NO:87, SEQ ID NO:88, SEQ ID NO:89, SEQ ID NO:90, SEQ ID NO:91, SEQ ID NO:92, SEQ ID NO:93, SEQ ID NO:94, SEQ ID NO:95 and SEQ ID NO:96, wherein at least one of said first and second amplification oligonucleotides optionally includes a base sequence that is recognized by an RNA polymerase.

5. A kit comprising:

said probe of claim 1; and

a second hybridization assay probe for use in determining the presence of HPV Type 18 nucleic acid in a sample, said second probe comprising an oligonucleotide up to 100 bases in length and having a base region that is at least 70% complementary to an at least 10 contiguous base region present in a second nucleic acid target region selected from the group consisting of SEQ ID NO:45, SEQ ID NO:46, SEQ ID NO:47, SEQ ID NO:48, SEQ ID NO:57, SEQ ID NO:58, SEQ ID NO:59, SEQ ID NO:60, SEQ ID NO:65, SEQ ID NO:66, SEQ ID NO:67, SEQ ID NO:68, SEQ ID NO:73, SEQ ID NO:74, SEQ ID NO:75, SEQ ID NO:76, SEQ ID NO:77, SEQ ID NO:78, SEQ ID NO:79, SEQ ID NO:80, SEQ ID NO:81, SEQ ID NO:82, SEQ ID NO:83 and SEQ ID NO:84, wherein said second probe forms a detectable probe:target duplex with said second target region under said conditions, and wherein said probe does not form a detectable probe:non-target duplex with nucleic acid from HPV Type 6, 11, 31, 33, 35, 39, 45, 51, 52 and/or 58 under said conditions.

6. The kit of claim 5 further comprising:

a first amplification oligonucleotide for use in amplifying HPV Type 16 nucleic acid in a sample, said first amplification oligonucleotide being up to 100 bases in length and having a base region that is at least 70% complementary to an at least 10 contiguous base region present in a nucleic acid target region selected from the group consisting of SEQ ID NO:1, SEQ ID NO:2, SEQ ID NO:3, SEQ ID NO:4, SEQ ID NO:13, SEQ ID NO:14, SEQ ID NO:15, SEQ ID NO:16, SEQ ID NO:21, SEQ ID NO:22, SEQ ID NO:23, SEQ ID NO:24, SEQ ID NO:37, SEQ ID NO:38, SEQ ID NO:39, SEQ ID NO:40, SEQ ID NO:85, SEQ ID NO:86, SEQ ID NO:87, SEQ ID NO:88, SEQ ID NO:89, SEQ ID NO:90, SEQ ID NO:91, SEQ ID NO:92, SEQ ID NO:93, SEQ ID NO:94, SEQ ID NO:95 and SEQ ID NO:96, wherein said first amplification oligonucleotide optionally includes a base sequence that is recognized by an RNA polymerase; and

a second amplification oligonucleotide for use in amplifying HPV Type 18 nucleic acid in a sample, said first amplification oligonucleotide being up to 100 bases in length and having a base region that is at least 70% complementary to an at least 10 contiguous base region present in a nucleic acid target region selected from the group consisting of SEQ ID NO:41, SEQ ID NO:42, SEQ ID NO:43, SEQ ID NO:44, SEQ ID NO:49, SEQ ID NO:50, SEQ ID NO:51, SEQ ID NO:52, SEQ ID NO:53, SEQ ID NO:54, SEQ ID NO:55, SEQ ID NO:56, SEQ ID NO:69, SEQ ID NO:70, SEQ ID NO:71, SEQ ID NO:72, SEQ ID NO:101, SEQ ID NO:102, SEQ ID NO:103, SEQ ID NO:104, SEQ ID NO:105, SEQ ID NO:106, SEQ ID NO:107, SEQ ID NO:108, SEQ ID NO:109, SEQ ID NO:110, SEQ ID NO:111, SEQ ID NO:112, SEQ ID NO:113, SEQ ID NO:114, SEQ ID NO:115 and SEQ ID NO:116, wherein said second amplification oligonucleotide optionally includes a base sequence that is recognized by an RNA polymerase.

7. The kit of claim 5 further comprising:

a first set of amplification oligonucleotides for use in amplifying HPV Type 16 nucleic acid in a sample, said first set including first and second amplification oligonucleotides, wherein each of said first and second amplification oligonucleotides is up to 100 bases in length and has a base region that is at least 70% complementary to

an at least 10 contiguous base region present in a nucleic acid target region selected from the group consisting of SEQ ID NO:1, SEQ ID NO:2, SEQ ID NO:3, SEQ ID NO:4, SEQ ID NO:13, SEQ ID NO:14, SEQ ID NO:15, SEQ ID NO:16, SEQ ID NO:21, SEQ ID NO:22, SEQ ID NO:23, SEQ ID NO:24, SEQ ID NO:37, SEQ ID NO:38, SEQ ID NO:39, SEQ ID NO:40, SEQ ID NO:85, SEQ ID NO:86, SEQ ID NO:87, SEQ ID NO:88, SEQ ID NO:89, SEQ ID NO:90, SEQ ID NO:91, SEQ ID NO:92, SEQ ID NO:93, SEQ ID NO:94, SEQ ID NO:95 and SEQ ID NO:96, wherein at least one of said first and second amplification oligonucleotides optionally includes a base sequence that is recognized by an RNA polymerase; and

a second set of amplification oligonucleotides for use in amplifying HPV Type 18 nucleic acid in a sample, said second set including third and fourth amplification oligonucleotides, wherein each of said third and fourth amplification oligonucleotides is up to 100 bases in length and has a base region that is at least 70% complementary to an at least 10 contiguous base region present in a nucleic acid target region selected from the group consisting of SEQ ID NO:41, SEQ ID NO:42, SEQ ID NO:43, SEQ ID NO:44, SEQ ID NO:49, SEQ ID NO:50, SEQ ID NO:51, SEQ ID NO:52, SEQ ID NO:53, SEQ ID NO:54, SEQ ID NO:55, SEQ ID NO:56, SEQ ID NO:69, SEQ ID NO:70, SEQ ID NO:71, SEQ ID NO:72, SEQ ID NO:101, SEQ ID NO:102, SEQ ID NO:103, SEQ ID NO:104, SEQ ID NO:105, SEQ ID NO:106, SEQ ID NO:107, SEQ ID NO:108, SEQ ID NO:109, SEQ ID NO:110, SEQ ID NO:111, SEQ ID NO:112, SEQ ID NO:113, SEQ ID NO:114, SEQ ID NO:115 and SEQ ID NO:116, wherein at least one of said third and fourth amplification oligonucleotides optionally includes a base sequence that is recognized by an RNA polymerase.

8. The kit of claim 5 further comprising a helper probe, said helper probe comprising an oligonucleotide up to 100 bases in length and having a base region that is at least 70% complementary to an at least 10 contiguous base region present in a third nucleic acid target region selected from the group consisting of SEQ ID NO:61, SEQ ID NO:62, SEQ ID NO:63, SEQ ID NO:64, SEQ ID NO:117, SEQ ID NO:118, SEQ ID NO:119, SEQ ID NO:120, SEQ ID NO:121, SEQ ID NO:122, SEQ ID NO:123, SEQ ID NO:124, SEQ ID NO:125, SEQ ID NO:126, SEQ ID NO:127 and SEQ ID NO:128, wherein said helper probe binds to said third region under said conditions, thereby facilitating hybridization of said second probe to said second target region.

9. The kit of claim 6 further comprising a helper probe, said helper probe comprising an oligonucleotide up to 100 bases in length and having a base region that is at least 70% complementary to an at least 10 contiguous base region present in a third nucleic acid target region selected from the group consisting of SEQ ID NO:61, SEQ ID NO:62, SEQ ID NO:63, SEQ ID NO:64, SEQ ID NO:117, SEQ ID NO:118, SEQ ID NO:119, SEQ ID NO:120, SEQ ID NO:121, SEQ ID NO:122, SEQ ID NO:123, SEQ ID NO:124, SEQ ID NO:125, SEQ ID NO:126, SEQ ID NO:127 and SEQ ID NO:128, wherein said helper probe binds to said third target region under said conditions, thereby facilitating hybridization of said second probe to said second target region.

10. The kit of claim 7 further comprising a helper probe, said helper probe comprising an oligonucleotide up to 100 bases in length and having a base region that is at least 70% complementary to an at least 10 contiguous base region present in a third nucleic acid target region selected from the group consisting of SEQ ID NO:61, SEQ ID NO:62, SEQ ID NO:63, SEQ ID NO:64, SEQ ID NO:117, SEQ ID NO:118, SEQ ID NO:119, SEQ ID NO:120, SEQ ID NO:121, SEQ ID NO:122, SEQ ID NO:123, SEQ ID NO:124, SEQ ID NO:125, SEQ ID NO:126, SEQ ID NO:127 and SEQ ID NO:128, wherein said helper probe binds to said third target region under said conditions, thereby facilitating hybridization of said second probe to said second target region.

11. A method for determining the presence of HPV Type 16 nucleic acid in a sample, said method comprising the steps of:

providing to a sample said probe of claim 1 under said conditions; and

determining whether said probe:target duplex has formed as an indication of the presence of HPV Type 16 nucleic acid in said sample.

12. The method of claim 11 further comprising providing to said sample an amplification oligonucleotide up to 100 bases in length and having a base region that is at least 70% complementary to an at least 10 contiguous base region present in a nucleic acid target region selected from the group consisting of SEQ ID NO:1, SEQ ID NO:2, SEQ ID NO:3, SEQ ID NO:4, SEQ ID NO:13, SEQ ID NO:14, SEQ ID NO:15, SEQ ID NO:16, SEQ ID NO:21, SEQ ID NO:22, SEQ ID NO:23, SEQ ID NO:24, SEQ ID NO:37, SEQ ID NO:38, SEQ ID NO:39, SEQ ID NO:40, SEQ ID NO:85, SEQ ID

NO:86, SEQ ID NO:87, SEQ ID NO:88, SEQ ID NO:89, SEQ ID NO:90, SEQ ID NO:91, SEQ ID NO:92, SEQ ID NO:93, SEQ ID NO:94, SEQ ID NO:95 and SEQ ID NO:96, wherein said amplification oligonucleotide optionally includes a base sequence that is recognized by an RNA polymerase.

13. The method of claim 11 further comprising providing to said sample a set of amplification oligonucleotides, said set including first and second amplification oligonucleotides, wherein each of said first and second amplification oligonucleotides is up to 100 bases in length and has a base region that is at least 70% complementary to an at least 10 contiguous base region present in a nucleic acid target region selected from the group consisting of SEQ ID NO:1, SEQ ID NO:2, SEQ ID NO:3, SEQ ID NO:4, SEQ ID NO:13, SEQ ID NO:14, SEQ ID NO:15, SEQ ID NO:16, SEQ ID NO:21, SEQ ID NO:22, SEQ ID NO:23, SEQ ID NO:24, SEQ ID NO:37, SEQ ID NO:38, SEQ ID NO:39, SEQ ID NO:40, SEQ ID NO:85, SEQ ID NO:86, SEQ ID NO:87, SEQ ID NO:88, SEQ ID NO:89, SEQ ID NO:90, SEQ ID NO:91, SEQ ID NO:92, SEQ ID NO:93, SEQ ID NO:94, SEQ ID NO:95 and SEQ ID NO:96, wherein at least one of said amplification oligonucleotides optionally includes a base sequence that is recognized by an RNA polymerase.

14. The method of claim 11 further comprising providing to said sample a second hybridization assay probe for use in determining the presence of HPV Type 18 nucleic acid in a sample, said second probe comprising an oligonucleotide up to 100 bases in length and having a base region that is at least 70% complementary to an at least 10 contiguous base region present in a second nucleic acid target region selected from the group consisting of SEQ ID NO:45, SEQ ID NO:46, SEQ ID NO:47, SEQ ID NO:48, SEQ ID NO:57, SEQ ID NO:58, SEQ ID NO:59, SEQ ID NO:60, SEQ ID NO:65, SEQ ID NO:66, SEQ ID NO:67, SEQ ID NO:68, SEQ ID NO:73, SEQ ID NO:74, SEQ ID NO:75, SEQ ID NO:76, SEQ ID NO:77, SEQ ID NO:78, SEQ ID NO:79, SEQ ID NO:80, SEQ ID NO:81, SEQ ID NO:82, SEQ ID NO:83 and SEQ ID NO:84, wherein said second probe forms a detectable probe:target duplex with said second target region under said conditions, and wherein said probe does not form a detectable probe:non-target duplex with nucleic acid from HPV Type 6, 11, 31, 33, 35, 39, 45, 51, 52 and/or 58 under said conditions.

15. The method of claim 14 further comprising providing to said sample a helper probe, said helper probe comprising an oligonucleotide up to 100 bases in length and having a base region that is at least 70% complementary to an at least 10 contiguous base region present in a third nucleic acid target region selected from the group consisting of SEQ ID NO:61, SEQ ID NO:62, SEQ ID NO:63, SEQ ID NO:64, SEQ ID NO:117, SEQ ID NO:118, SEQ ID NO:119, SEQ ID NO:120, SEQ ID NO:121, SEQ ID NO:122, SEQ ID NO:123, SEQ ID NO:124, SEQ ID NO:125, SEQ ID NO:126, SEQ ID NO:127 and SEQ ID NO:128, wherein said helper probe binds to said third region under said conditions, thereby facilitating hybridization of said second probe to said second target region.

16. The method of claim 14 further comprising providing to said sample:

a first amplification oligonucleotide for use in amplifying HPV Type 16 nucleic acid, said first amplification oligonucleotide being up to 100 bases in length and having a base region that is at least 70% complementary to an at least 10 contiguous base region present in a nucleic acid target region selected from the group consisting of SEQ ID NO:1, SEQ ID NO:2, SEQ ID NO:3, SEQ ID NO:4, SEQ ID NO:13, SEQ ID NO:14, SEQ ID NO:15, SEQ ID NO:16, SEQ ID NO:21, SEQ ID NO:22, SEQ ID NO:23, SEQ ID NO:24, SEQ ID NO:37, SEQ ID NO:38, SEQ ID NO:39, SEQ ID NO:40, SEQ ID NO:85, SEQ ID NO:86, SEQ ID NO:87, SEQ ID NO:88, SEQ ID NO:89, SEQ ID NO:90, SEQ ID NO:91, SEQ ID NO:92, SEQ ID NO:93, SEQ ID NO:94, SEQ ID NO:95 and SEQ ID NO:96, wherein said first amplification oligonucleotide optionally includes a base sequence that is recognized by an RNA polymerase; and

a second amplification oligonucleotide for use in amplifying HPV Type 18 nucleic acid, said second amplification oligonucleotide being up to 100 bases in length and having a base region that is at least 70% complementary to an at least 10 contiguous base region present in a nucleic acid target region selected from the group consisting of SEQ ID NO:41, SEQ ID NO:42, SEQ ID NO:43, SEQ ID NO:44, SEQ ID NO:49, SEQ ID NO:50, SEQ ID NO:51, SEQ ID NO:52, SEQ ID NO:53, SEQ ID NO:54, SEQ ID NO:55, SEQ ID NO:56, SEQ ID NO:69, SEQ ID NO:70, SEQ ID NO:71, SEQ ID NO:72, SEQ ID NO:101, SEQ ID NO:102, SEQ ID NO:103, SEQ ID NO:104, SEQ ID NO:105, SEQ ID NO:106, SEQ ID NO:107, SEQ ID NO:108, SEQ ID NO:109, SEQ ID NO:110, SEQ ID NO:111, SEQ ID NO:112, SEQ ID NO:113, SEQ ID NO:114, SEQ

ID NO:115 and SEQ ID NO:116, wherein said second amplification oligonucleotide optionally includes a base sequence that is recognized by an RNA polymerase.

17. The method of claim 16 further comprising providing to said sample a helper probe, said helper probe comprising an oligonucleotide up to 100 bases in length and having a base region that is at least 70% complementary to an at least 10 contiguous base region present in a third nucleic acid target region selected from the group consisting of SEQ ID NO:61, SEQ ID NO:62, SEQ ID NO:63, SEQ ID NO:64, SEQ ID NO:117, SEQ ID NO:118, SEQ ID NO:119, SEQ ID NO:120, SEQ ID NO:121, SEQ ID NO:122, SEQ ID NO:123, SEQ ID NO:124, SEQ ID NO:125, SEQ ID NO:126, SEQ ID NO:127 and SEQ ID NO:128, wherein said helper probe binds to said third region under said conditions, thereby facilitating hybridization of said second probe to said second target region.

18. The method of claim 14 further comprising providing to said sample:

a first set of amplification oligonucleotides for use in amplifying HPV Type 16 nucleic acid, said first set including first and second amplification oligonucleotides, wherein each of said first and second amplification oligonucleotides is up to 100 bases in length and has a base region that is at least 70% complementary to an at least 10 contiguous base region present in a nucleic acid target region selected from the group consisting of SEQ ID NO:1, SEQ ID NO:2, SEQ ID NO:3, SEQ ID NO:4, SEQ ID NO:13, SEQ ID NO:14, SEQ ID NO:15, SEQ ID NO:16, SEQ ID NO:21, SEQ ID NO:22, SEQ ID NO:23, SEQ ID NO:24, SEQ ID NO:37, SEQ ID NO:38, SEQ ID NO:39, SEQ ID NO:40, SEQ ID NO:85, SEQ ID NO:86, SEQ ID NO:87, SEQ ID NO:88, SEQ ID NO:89, SEQ ID NO:90, SEQ ID NO:91, SEQ ID NO:92, SEQ ID NO:93, SEQ ID NO:94, SEQ ID NO:95 and SEQ ID NO:96, wherein at least one of said first and second amplification oligonucleotides optionally includes a base sequence that is recognized by an RNA polymerase; and

a second set of amplification oligonucleotides for use in amplifying HPV Type 18 nucleic acid, said second set including third and fourth amplification oligonucleotides, wherein each of said third and fourth amplification oligonucleotides is up to 100 bases in length and has a base region that is at least 70% complementary to an at least 10 contiguous base region present in a nucleic acid target region selected from

the group consisting of SEQ ID NO:41, SEQ ID NO:42, SEQ ID NO:43, SEQ ID NO:44, SEQ ID NO:49, SEQ ID NO:50, SEQ ID NO:51, SEQ ID NO:52, SEQ ID NO:53, SEQ ID NO:54, SEQ ID NO:55, SEQ ID NO:56, SEQ ID NO:69, SEQ ID NO:70, SEQ ID NO:71, SEQ ID NO:72, SEQ ID NO:101, SEQ ID NO:102, SEQ ID NO:103, SEQ ID NO:104, SEQ ID NO:105, SEQ ID NO:106, SEQ ID NO:107, SEQ ID NO:108, SEQ ID NO:109, SEQ ID NO:110, SEQ ID NO:111, SEQ ID NO:112, SEQ ID NO:113, SEQ ID NO:114, SEQ ID NO:115 and SEQ ID NO:116, wherein at least one of said third and fourth amplification oligonucleotides optionally includes a base sequence that is recognized by an RNA polymerase.

19. The method of claim 18 further comprising providing to said sample a helper probe, said helper probe comprising an oligonucleotide up to 100 bases in length and having a base region that is at least 70% complementary to an at least 10 contiguous base region present in a third nucleic acid target region selected from the group consisting of SEQ ID NO:61, SEQ ID NO:62, SEQ ID NO:63, SEQ ID NO:64, SEQ ID NO:117, SEQ ID NO:118, SEQ ID NO:119, SEQ ID NO:120, SEQ ID NO:121, SEQ ID NO:122, SEQ ID NO:123, SEQ ID NO:124, SEQ ID NO:125, SEQ ID NO:126, SEQ ID NO:127 and SEQ ID NO:128, wherein said helper probe binds to said third region under said conditions, thereby facilitating hybridization of said second probe to said second target region.